



Agnitio BiolC System Service Manual

Agnitio Science & Technology, Inc.

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This document contains the most current information available at the time of publication. When new and/or revised information become available, this entire document will be updated and distributed to customers.

User Safety

This section includes important information for the safety of the user.

Read carefully before continuing. When using instruments, a number of fundamental safety rules must be observed, including the following:

- Read all of the instructions prior to use
- Do not immerse the instrument in liquid. See the instructions for maintenance.
- Place the instrument on a flat, stable surface that can hold 50kg or more.
- Before installation, ensure instrument is at least 20 cm from the wall or any object on the counter/table.
- Avoid dust, blood, reagents, magnetic fields, excessive humidity and direct sunlight since they may cause operational errors.
- Stay away from the running fan on the backside of instrument to avoid the potential risk.
- Operate the instrument at room temperature (Between 15 °C – 28 °C)
- Unplug the instrument from the power outlet when not in use or prior to cleaning.
- Never use the instrument with the damaged cable or plug, or when there is any malfunction have occurred or if the instrument has been damaged in any way.
- Use maximum care when moving the instrument.
- Do not use the instrument for purpose other than those it has been designed for.
- Do not put foreign objects inside the instrument or open the door during the automatic operation.
- **Electronic Connection:**
 - ✓ This instrument must be properly grounded. In the event of short circuit, the ground connection reduces the risk of electronic shock, allowing the electronic current to be dispersed.
 - ✓ The plug must be connected to a power outlet that has been correctly installed and grounded. Improper use of ground wire may lead to risk of electronic shock.
 - ✓ If you are unsure if the power outlet is grounded, contact qualified electrician.
 - ✓ Do not use multiple extension cords to power the instrument.
 - ✓ Ensure the power switch is OFF before you insert the power cord.
 - ✓ Do not use a wall socket with multiple outlets.
 - ✓ Handle of power cable with care; avoid pulling and twisting the cable.
 - ✓ The attached power cable is for used in Taiwan only. For other regions, please use an appropriate regional power cable. Failure to do so will result to severe damage to the instrument.
 - ✓ This instrument is not equipped with an emergency stop button. For an emergency stop, turn the instrument off using the Power Switch button.

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1

1. System Overview

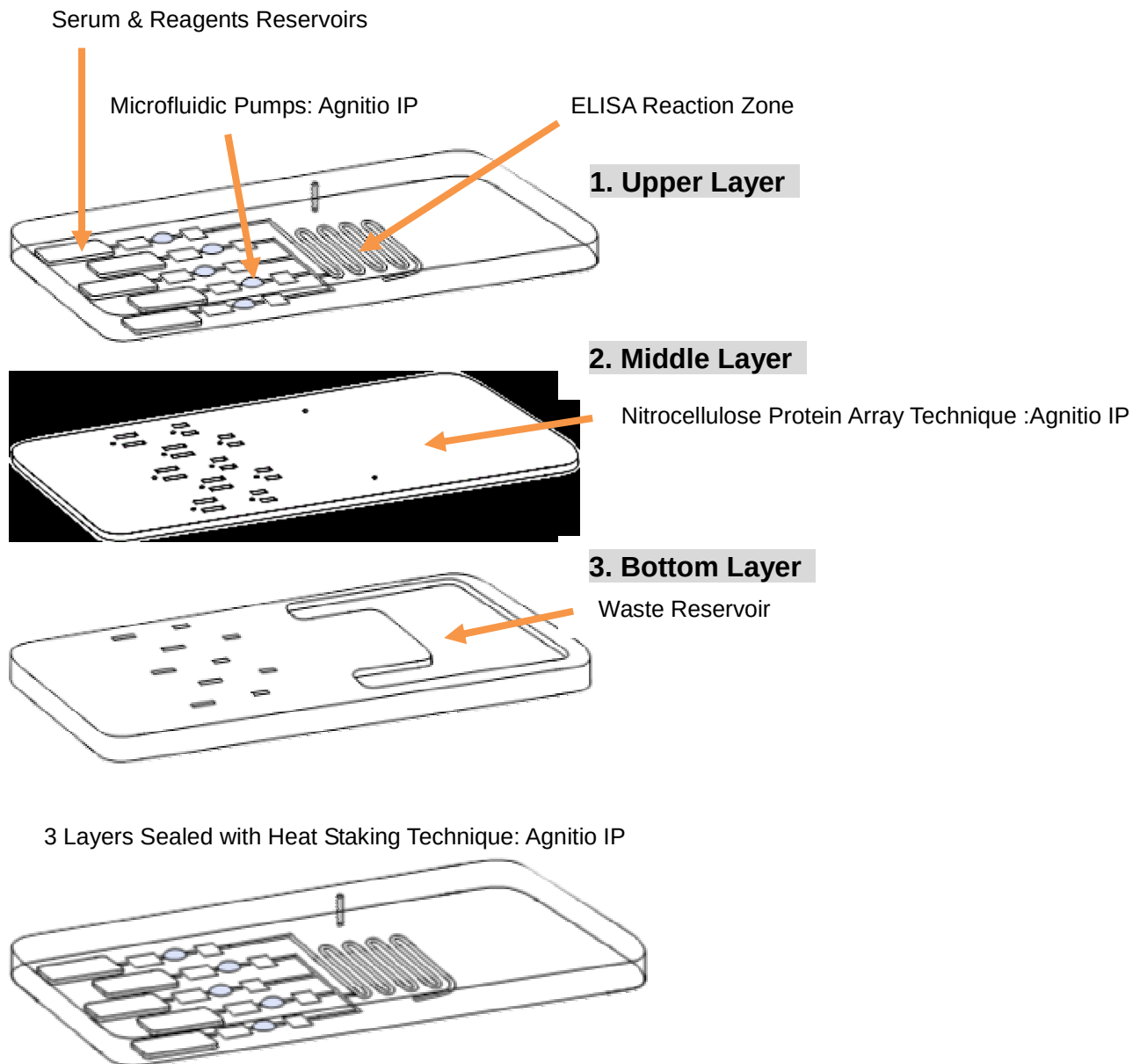
Agnitio BioIC System includes Agnitio BioIC analyzer and Agnitio BioIC pumping machine that cooperate with LabIT™ software and Agnitio Allergen Specific IgE Detection Kit to perform the blood allergen specific IgE assay.

Agnitio BioIC assay is an in vitro test, which provides semi quantitative measurement of circulating allergen specific IgE antibodies in human serum. The BioIC assay is intended to assist in the clinical diagnosis of IgE-mediated allergic disorders.

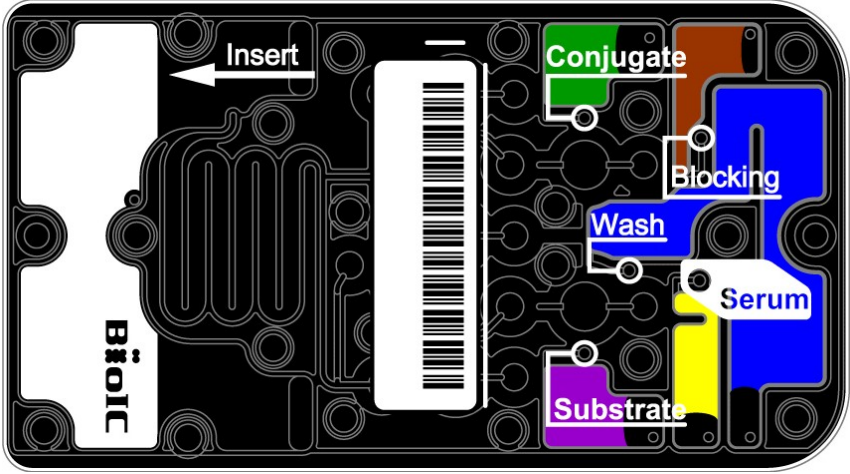
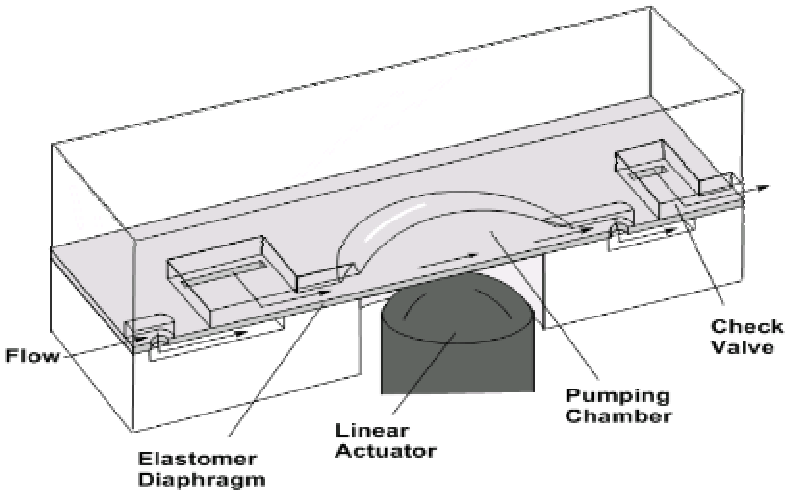
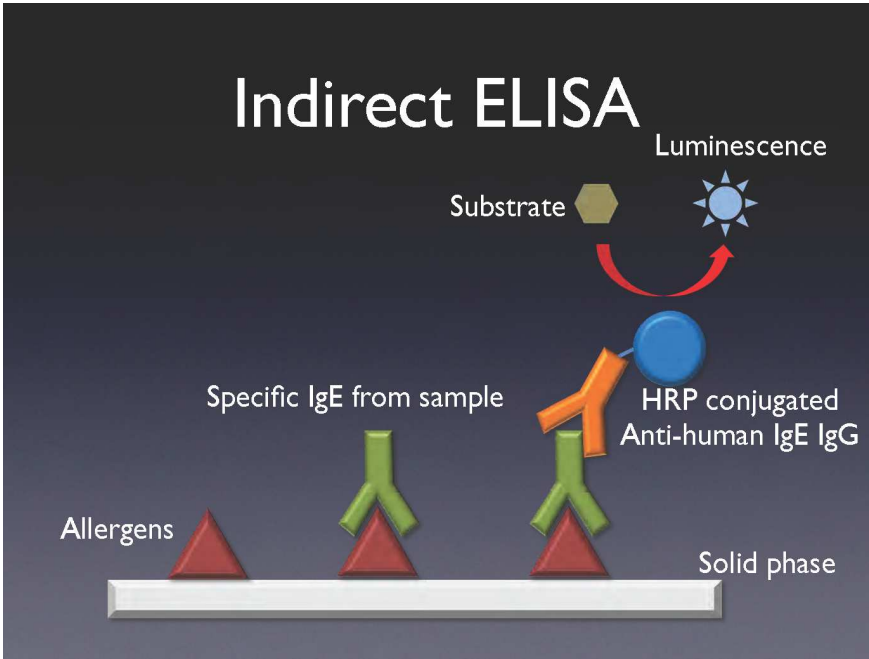
The BioIC System utilizes a microfluidic cartridge to perform an automated ELISA reaction. Each cartridge contains an array of microfluidic pumps and valves, a microfluidic channel network, reagent storage reservoirs, a protein microarray reaction zone, and a waste storage reservoir. All reagents are pumped from their respected reservoirs into the reaction zone containing a protein microarray in order to carry out a multiplexed ELISA reaction with chemiluminescence based detection. Results are captured simultaneously and data analysis is performed by the LabIT™ software.

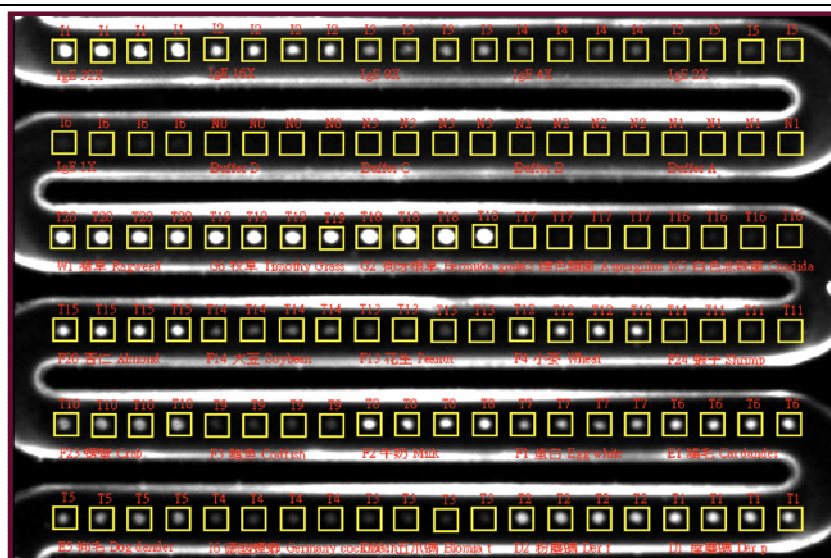
1.1 Principle of Procedure

1.1.1 BioIC cartridge structure

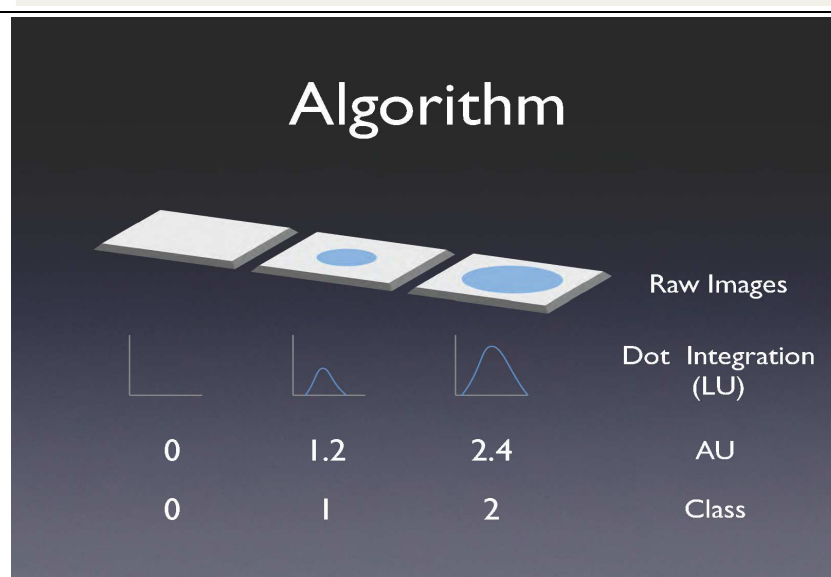


1.1.2 BioIC Assay Detection Principle

	BioIC microfluidic cartridge
	Cross sectional schematic of pump structure
	Indirect ELISA



CCD Camera raw Image



LabIT software converts CCD raw images LU to AU and generate the 6 Classes semi-quantitative report automatically.

Risk of allergic symptoms after allergen exposure as indicated by allergen-specific IgE antibody grade

Grade	IU/mL	Approximate risk of symptoms after exposure
0	<0.35	Extremely unlikely
1	0.35-0.7	Mild, possible
2	0.7-3.5	Mild, more possible
3	3.5-17.5	Moderate, likely
4	17.5-50	Moderate, more likely
5	50-100	Very likely
6	>100	Extremely likely

Clin Exp Immunol 2008; 153:18

BiolC report

1.2 Specifications

	1.2.1 Agnitio BioIC Analyzer	1.2.2 Agnitio BioIC Pumping Machine
Module	BA-G2000	BA-G2000 Pumping Machine
Appearance:	See page 6	See page 6
Case:	Casting Aluminum Alloys	Casting Aluminum Alloys
Dimension:	33L cm x 22W cm x 32H cm	16L cm x 21W cm x 17H cm
Weight:	Approximately 12 Kg	Approximately 5 Kg
Power Voltage:	AC100V-AC 240V (50/60Hz)	AC100V-AC 240V (50/60Hz)
Fuse:	AC 250V 4A	N/A
Consumption Electric Power:	200W	60W
CCD Camera:	FLI	N/A
Operation Temperature:	15°C -28°C	15°C -28°C

	1.2.3 Agnitio Allergen Specific IgE Detection Kit
Module	AD40
Appearance:	See page 31
Kit Package Dimension:	61L cm x 52W cm x 39H cm
Weight:	Approximately 650 gm
Contents of kit:	See page 31
Delivery and Storage Temperature:	2°C -8°C

1.3 Agnitio BioIC System Overview



1. Agnitio BioIC Analyzer

Agnitio BioIC Analyzer can perform the default LabIT ELISA assays.

2. Agnitio Pumping Machine

Agnitio Pumping Machine is designed to perform partial default LabIT[®] ELISA steps, and it has to be used together with BioIC analyzer to complete the rest of default LabIT[™] ELISA steps (final CCD imaging and generate report) . Small labs (10 sample/ per day) are recommended to use 1 analyzer +2 Pumping Machines. Bigger size labs or teaching hospitals are recommended to use 1 Analyzers + 6 Pumping Machines.

3. Barcode Reader

Agnitio BioIC assay requires barcode reader to loading patient's data.

1.4 Accessories

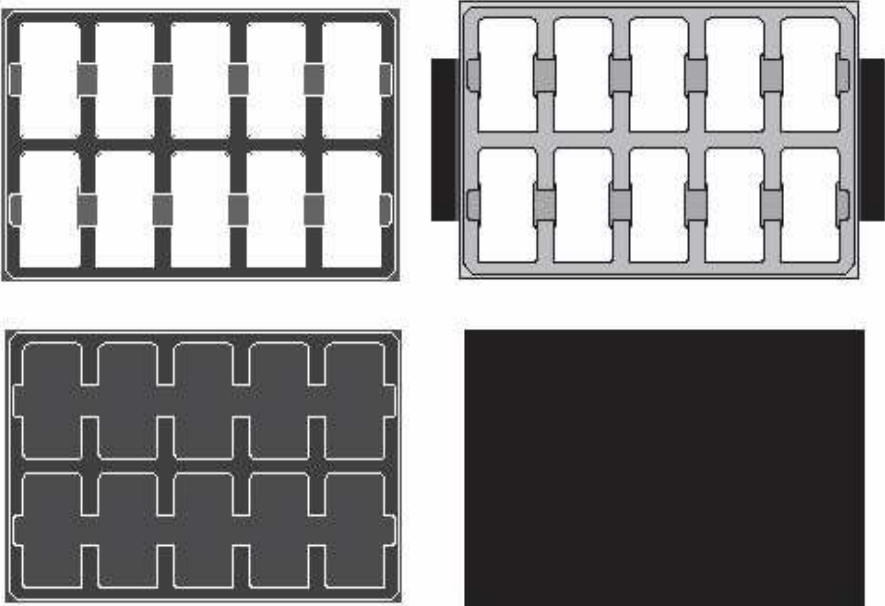
1.4.1 Agnitio BioIC Analyzer

Accessories	Photo	Qty
RS232 cable		1
USB cable (is linked with Analyzer)		1
Barcode Reader (To be linked with PC)		1
Power Cable (US cable plug)		1

1.4.2 Agnitio Pumping Machine

Accessories	Photo	Qty
Power Brick		1
Power Cable (subject to change according to the region)		1

1.4.3 Individual Accessories

	Photo	Qty
BiolC Tray		1



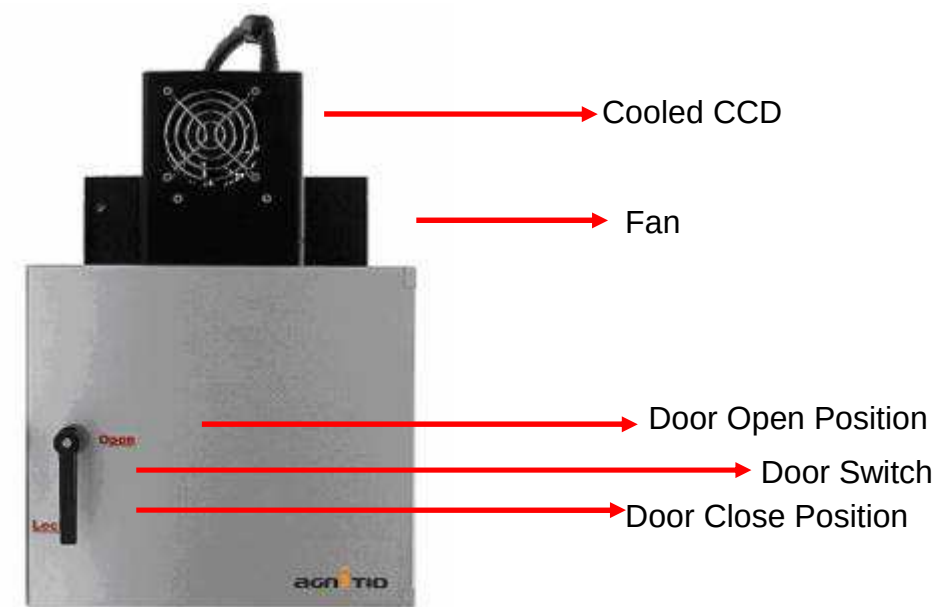
2. Identification of Parts

2.1 BioIC BA-G2000 Analyzer

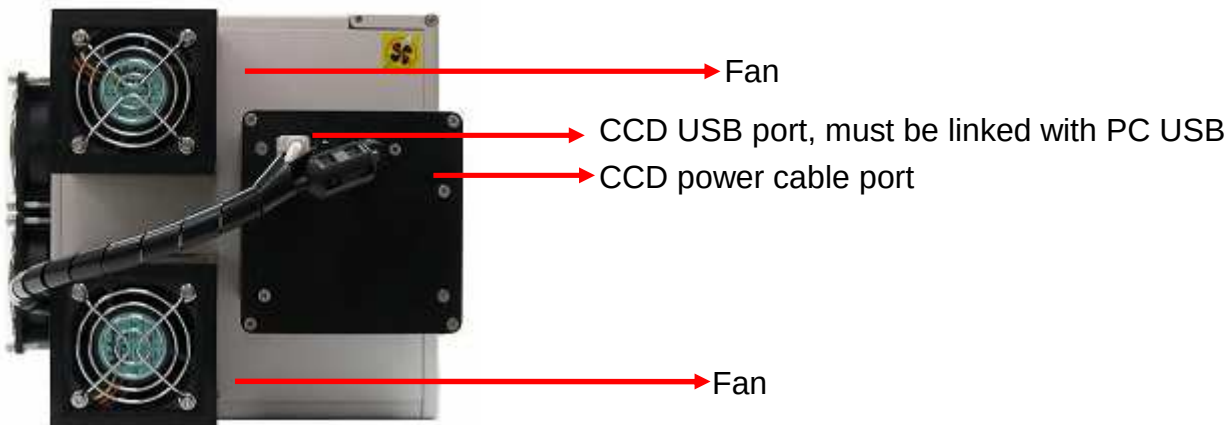
2.2 BioIC BA-G2000 Pumping Machine

2.1 BioIC BA-G2000 Analyzer

2.1.1 Front View



2.1.2 Top View



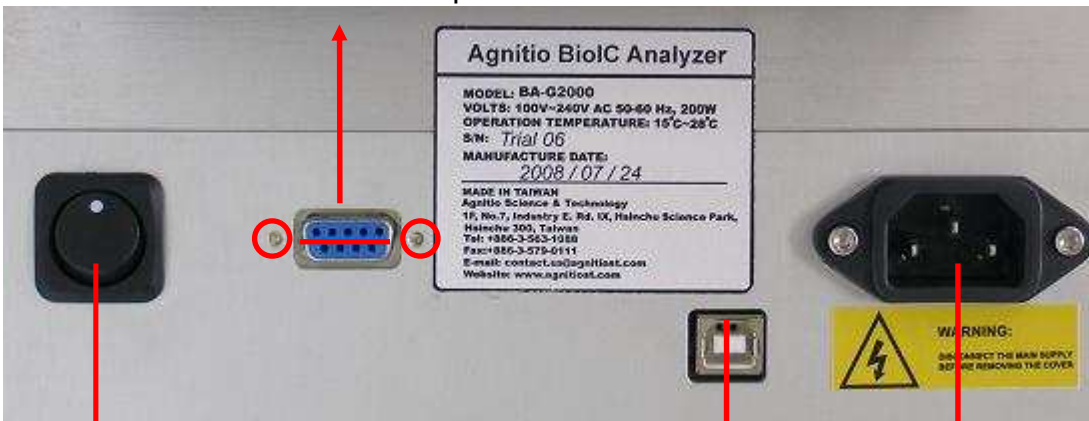
2.1.3 Back View



Fan

2.1.4 Connection ports of BiolC BA-G2000 Analyzer

1. RS232 port



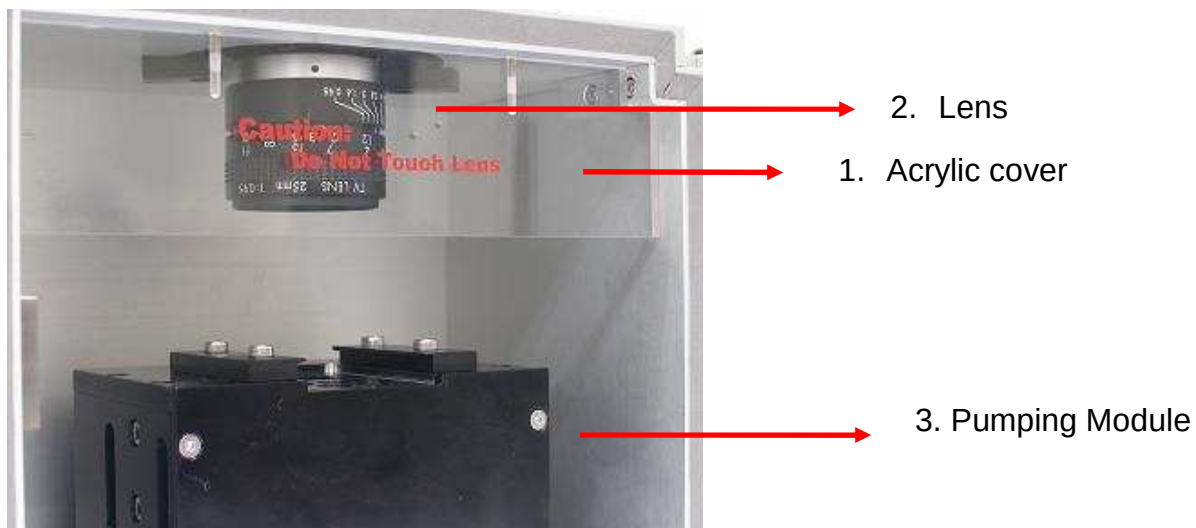
4. USB port

2. AC Power

3. Power Switch

1. RS232 port should be linked with PC COM1
2. Power Switch: Check all connections are in the proper positions before turning ON
3. USB port is for linking the CCD camera, if the USB of CCD camera is already connected with the computer(priority), it's not necessarily to use this port to link again.

2.1.4 Inner View



1. Acrylic cover: Acrylic cover to protect the CCD lens to be moved and adjusted
2. Please insert the cartridge according to the direction and it will be automatically locked when the door is close.

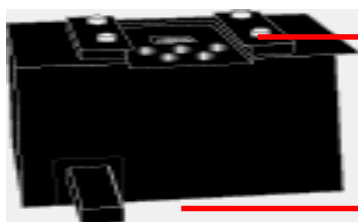
2.1.5 Lens



Focus

Note: Do not adjust CCD Lens Focus

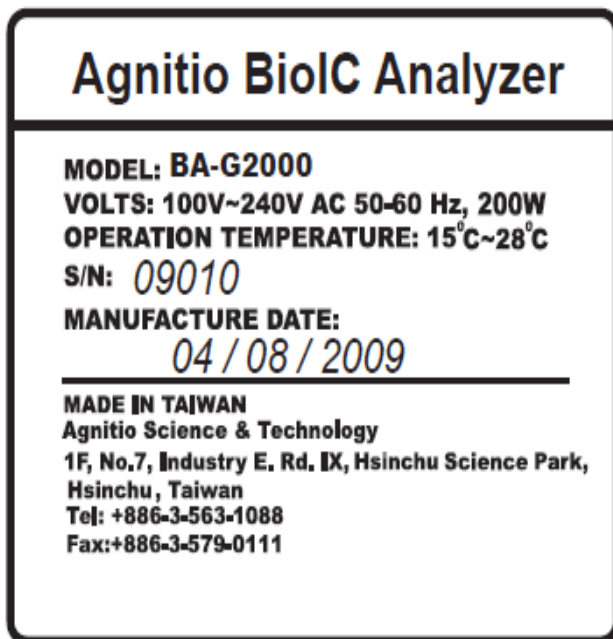
2.1.6 Pumping Module



Cartridge Slot

Pumping Module Switch

2.1.7 Labeling



Note : Disconnect the main power supply before remove the cover



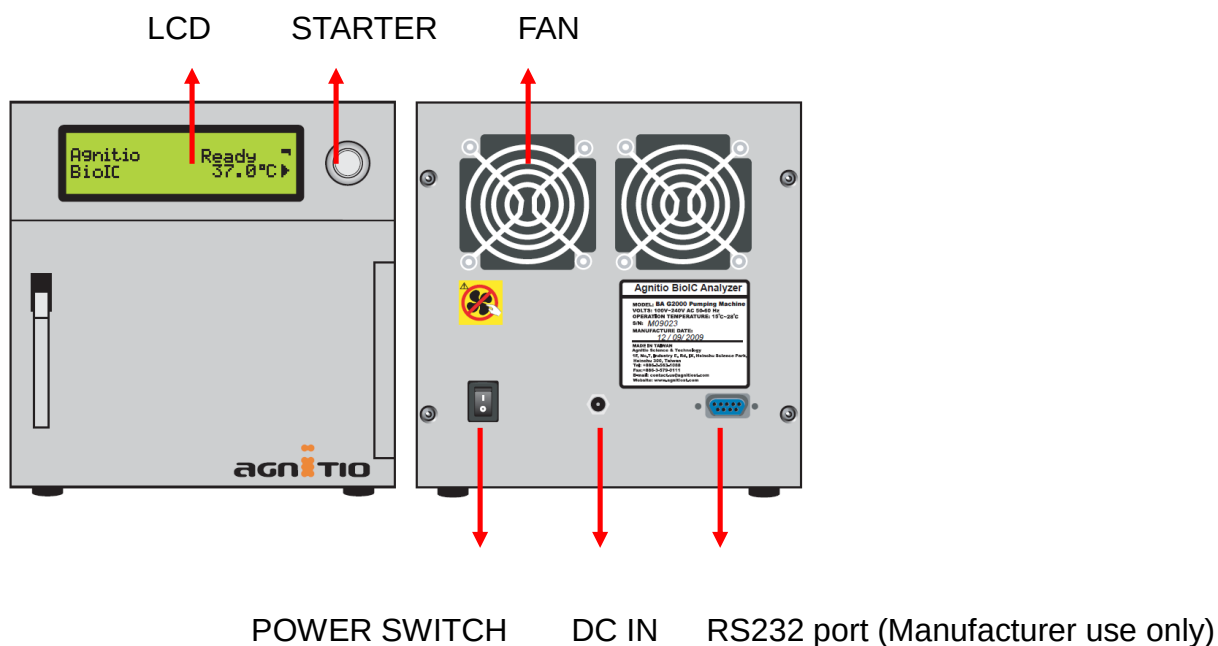
2.2 BioIC BA-G2000 Pumping Machine

Each BioIC analyzer can be installed with maximum 6 units of pumping machines according to the sample size of the laboratories. BioIC system allows users to perform maximum 7 BioIC cartridges in the same time.

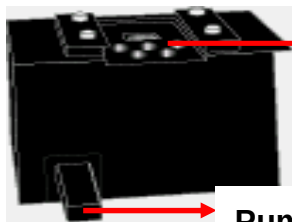
BioIC pumping machine has its own built in LabIT™ software and individual power supply. BioIC BA-G2000 pumping machine is designed to perform a subset of the LabIT™ ELISA steps, it can be only used together with BioIC BA-G2000 analyzer to complete the LabIT™ ELISA steps(add substrate, CCD imaging and generate the report).

2.2.1 Front View and Back View

The LCD display in front of the pumping machine provides easy to read information including “Reaction Temperature”, “Ready”, “Door open” etc.



2.2.2 Inner View



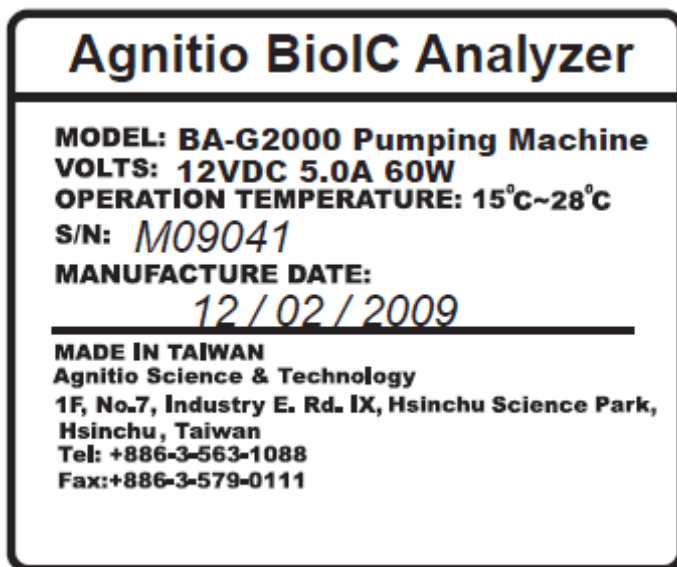
Cartridge Slot

Pumping Module Switch

Note:

1. Make sure insert BiolC cartridge along the right direction and also push it till the bottom of **cartridge slot**.
2. Then make sure front door is closed properly. As soon as close the front door, **pumping module switch** will lift up the heater and solenoids to the right positions in the same time. And the firmware will control heating temperature at constant $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ and drive the solenoid's microfluidic actuation.

2.2.3 Labeling



Do not touch the Fan during the system running BiolC assay

3

3. Installation Instructions

3.1 Installation of BioIC Analyzer & Pumping Machine

3.2 Installation of LabIT™ software

3.3 BioIC Analyzer CCD leak test, position alignment & focus test

3.1 Installation of BioIC Analyzer & Pumping Machine

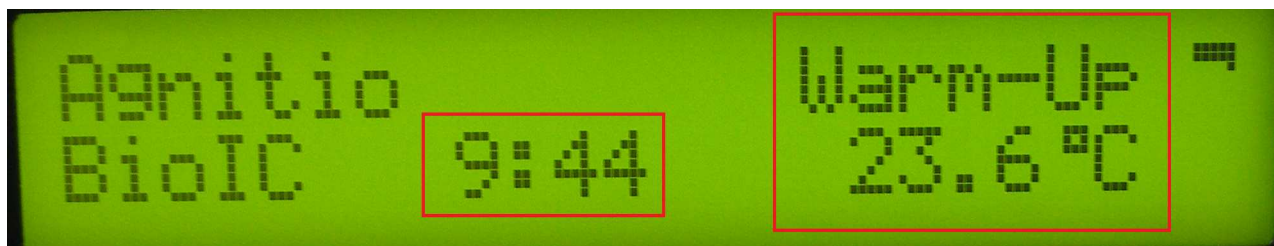
3.1.1 Installation of BA-G2000 Pumping Machine

Step1. Connect the power brick and power cable with BA-G2000 Pumping Machine

Step2. Connect the Pumping Machine to power supply (100V~240V AC, 50/60 Hz, 1.4A)



Step 3. Turn on the Power Switch , Check the LCD display information.



Step 4. Open front door; check if LCD display shows the door open signal



Step 5. Waiting Heater temperature reach to 37°C±1°C and LCD display shows “READY”



3.1.2 Installation of BA-G2000 BioIC Analyzer

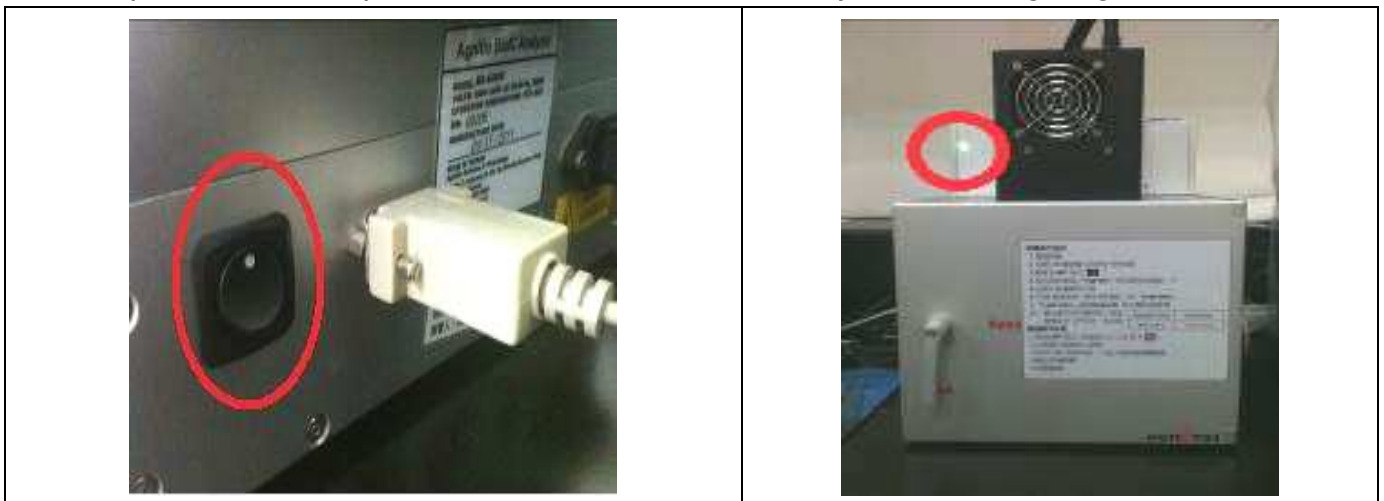
- Step1: Connect power brick and RS232 with BioIC Analyzer
- Step 2: USB cable is linked with Analyzer



- Step 3: Connect CCD power cable brick and USB with PC
- Step 4: Well connect the RS232 between Analyzer and PC.



- Step 5: Turn on the power switch and make sure analyzer LED is lighting on.



Please make sure all the PC equipments are well installed and the connections of all cables are available.

3.2 Installation of LabIT™ software

1. Install CCD driver. Click the FLI-Installer.exe (32 bit or 64 bit)
2. Install latest version of Donetfx.exe (32 bit or 64 bit)
3. Copy PDF reader software (FoxitReader.exe) to C:\Program Files\
4. Copy the whole LabIT file to Disc D
5. Copy the CCD calibration image to the file (\\LabIT\Bin\Distributor), and change the file name to "cal.tif".
6. Search from the file (\\ LabIT\bin\Distributor) for prototype.exe, and create a shortcut onto the desktop.
7. Click the icon on the desktop, to make sure the process is completed.

Notifications of LabIT™ software installation:

- ✓ LabIT software default com port is COM1. If using another COM port, please close the program and update the file (D: \ LabIT\bin\Release\ prototype. setting)
- ✓ If error message "Dark Frame Expired" pop up. Click Tools/System Test/Leak to update the image (4 minutes)
- ✓ Simple mode (Tools/Preferences/User Mode) is for user use, Advanced mode (Tools/Preferences/User Mode) is for engineer use (for modifying faled data)
Password for Advanced mode is "**advanced**"
- ✓ Brief function for tool bar

File/Load Application Data - Loading applicaton data

Screen/ - switch the screen between running program and image analysis

Image/ - loading image

Results/ - disable

Tools/Preferences/General - switch between Advanced mode and Simple mode

Tools/Preferences/Output - select working output directory

Tools/Preferences/Alarm - set alarm duration

Tools/Preferences/System Test/Focus - test image focus

Tools/Preferences/System Test/Leak - leak test and dark frame updated

Tools/Preferences/System Test/Alignment - test alignment

Tools/Re-Connect Analyzer/ - reconnect analyzer when losing connection including CCD and heater.

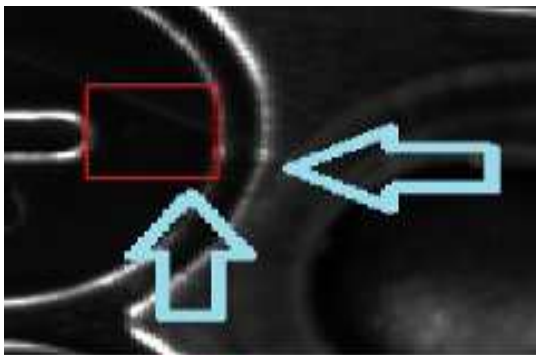
3.3 BioIC Analyzer CCD leak test, position alignment & focus test

3.3.1 CCD Camera Leak Test

- Close analyzer front door, and setting LabIT™ CCD temperature as -15°C , wait until CCD temperature reach to -15°C
- Perform 4 minutes Leak Test via: Tools\ System test\ Leak, LabIT™ will start leak test automatically.
- If Leak Test success : LabIT™ software will pop up “ Leak Test Pass” (below 20)
- If Leak Test failed, please refer to the trouble shooting section.

3.3.2 CCD Camera Position Alignment & Focus Test

- Enter: Tools > Preferences, click Advanced mode. Enter code number as “advanced” , Enter Tools > System Test
- Insert alignment cartridge (alignment cartridge should be provided by manufacturer) into cartridge slot and open the analyzer front door slightly.
- Click “Reset ”and press “Expose” to capture the CCD image.
- Press “ Toggle” to present captured CCD image’s alignment positions in red squares as below photos



CCD image alignment positions in red square



Lens focus should be clear

4

4. Operation

Section 4 Operation is purpose to assist laboratory technician to perform the blood allergen specific IgE assay with Agnitio BioIC system.

4.1 Software LabIT™

4.2 Assay Procedures of BioIC Specific-IgE Allergen Detection Kit

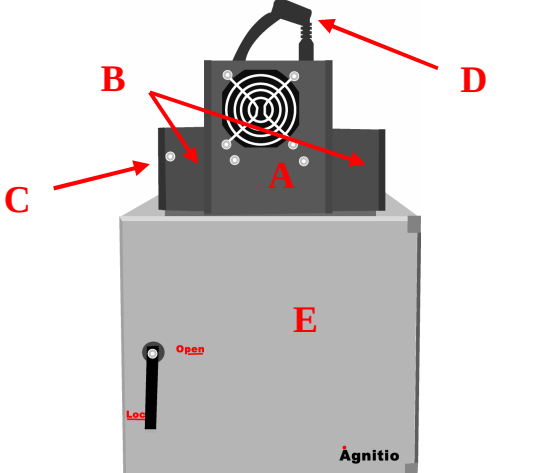
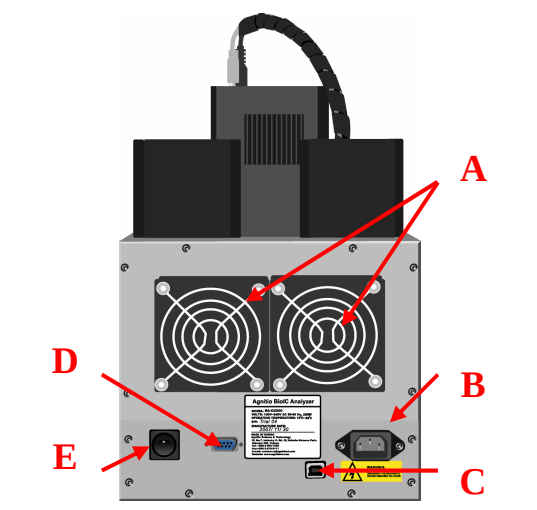
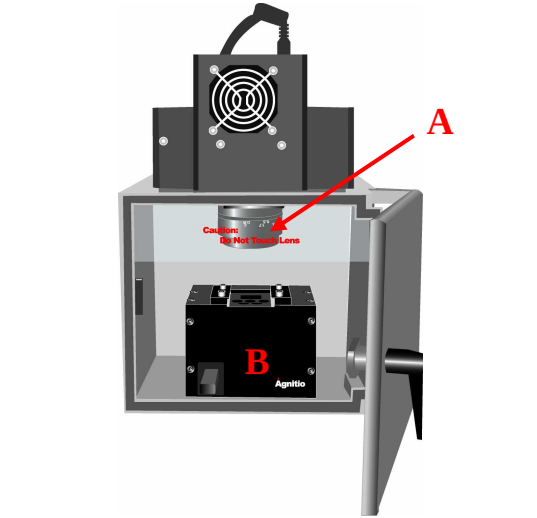
Before conducting any tests, please be sure that you have gone through this instruction manual and performing the testing accordingly.

This software require the system of Windows XP or Windows 7 and the computer requires to equipt with 1 COM1 port and 2 USB port to operate the entire system.

For users, **Simple** version is suitable for them, the **Advanced** version is for engineering use only.

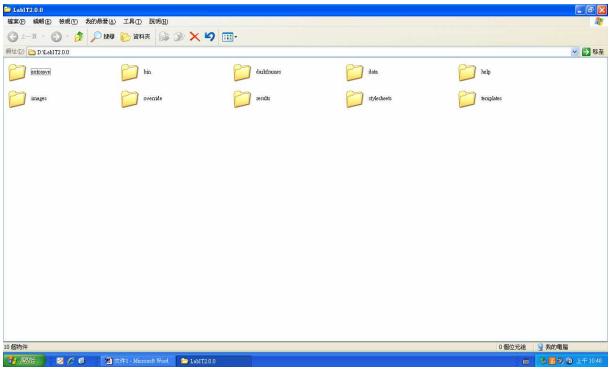
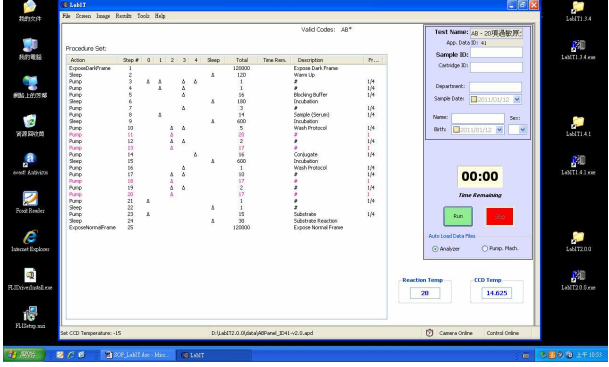
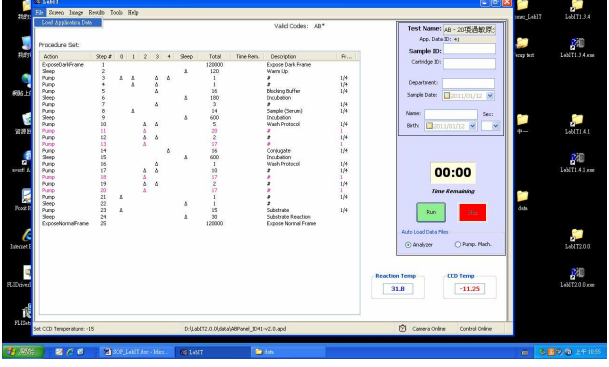
4.1 Software LabIT™

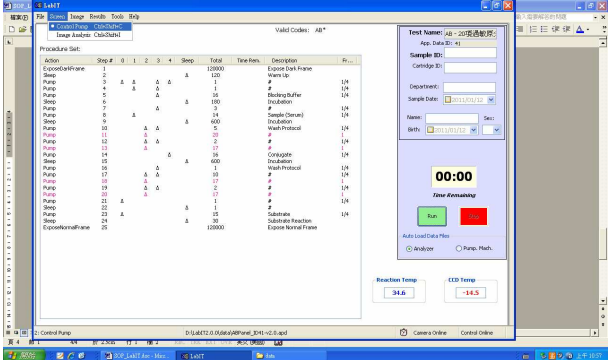
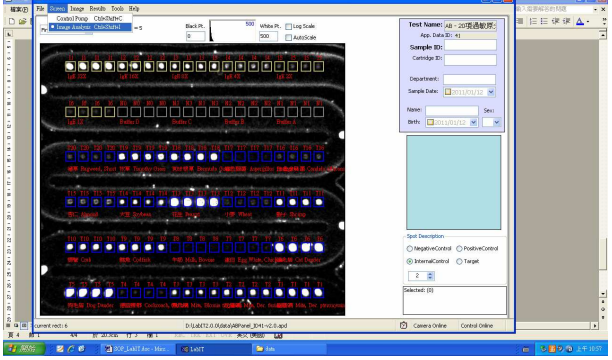
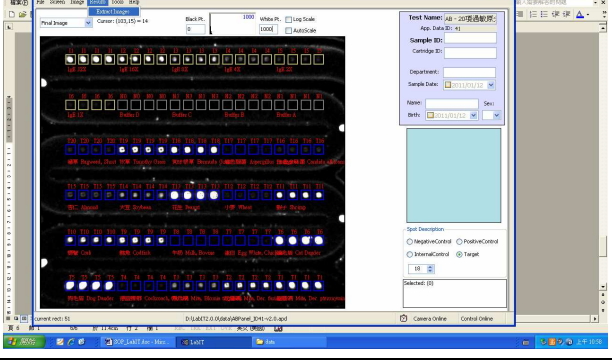
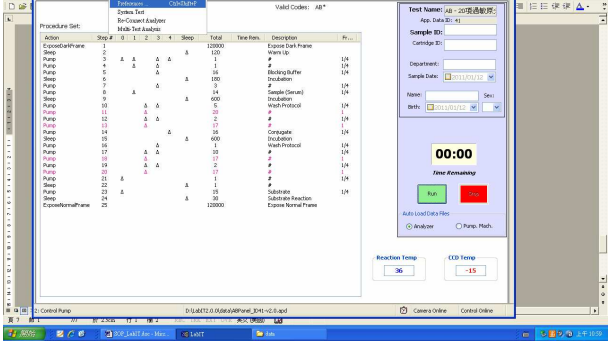
4.1.1 Agnitio BioIC Analyzer

	Front Site: (A) CCD Camera (B) Cooler Fans (C) Indicated Light On – Stand by Flash – Running (D) Cable of CCD Please connect properly when installation (E) Front Door
	Rear Site: (A) Fans (B) Power cable Port (C) USB Port (D) RS232 Port (E) Switch
	Inside: (A) Lens (already adjusted) Caution: Please do not touch lens (B) Pumping Module Control all the procedures of operation Caution: Please make sure the cartridge is sliding into the proper position

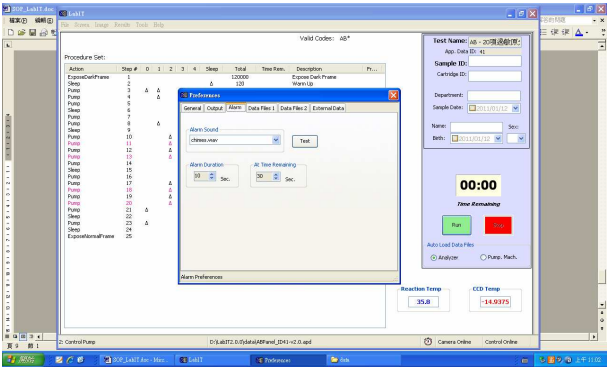
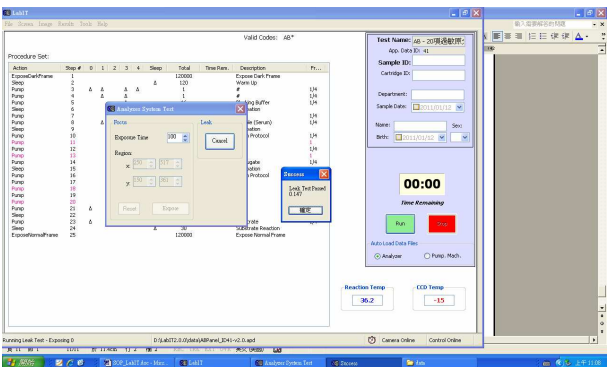
4.1.2 Operating and Analysis software: LabIT™

Items of Menu Bar

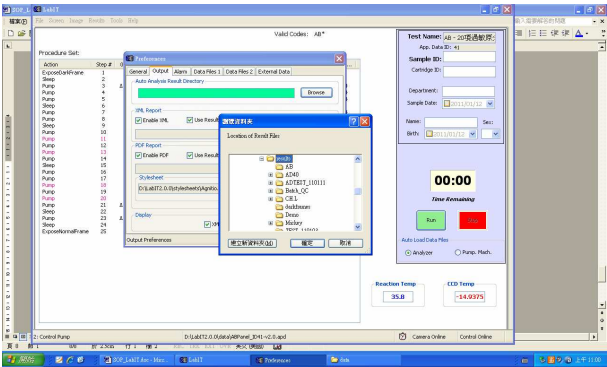
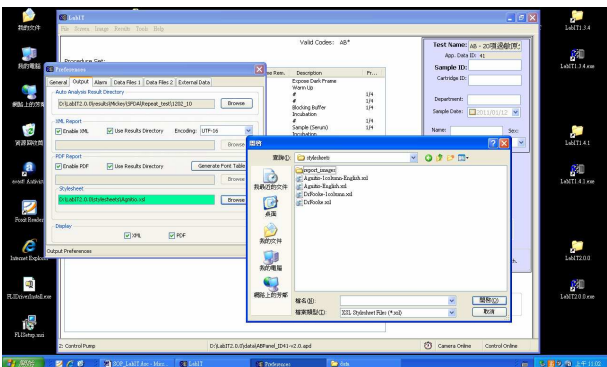
Items	Illustration	Notes
1		➤ The folders for LabIT™ including auto save, bin, dark frames, data, images, override, results, and style sheets
2		➤ Execute LabIT™(a short cut called LabIT on desktop)
3		➤ The Menu bar including File, Screen, Image (not available for Simple Mode) , Results, Tools and Help (Program description)
4		➤ File / Load Application Data ➤ Application Data is the program for test procedure and data analysis pattern ➤ Load application data from folder called Data ➤ For LabIT using the function of auto load application data

5		➤ Screen Switch ➤ Screen / Control Pump display the experiment protocol
6		➤ Screen Switch ➤ Screen / Image Analysis display the image and data analysis pattern
7		➤ Results / Extract Images - Extract the existed results
8		➤ Tools / - Including Preferences, System Test, Re-Connect Analyzer, and Multi-Test Analysis

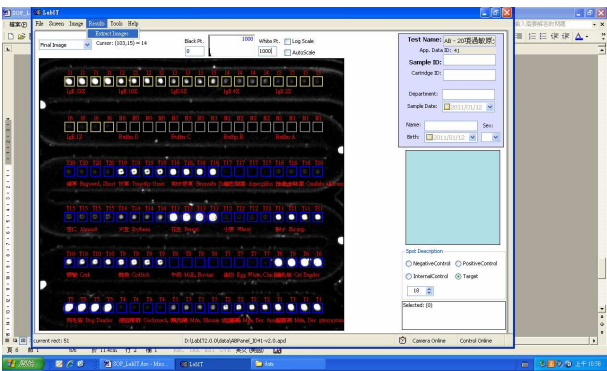
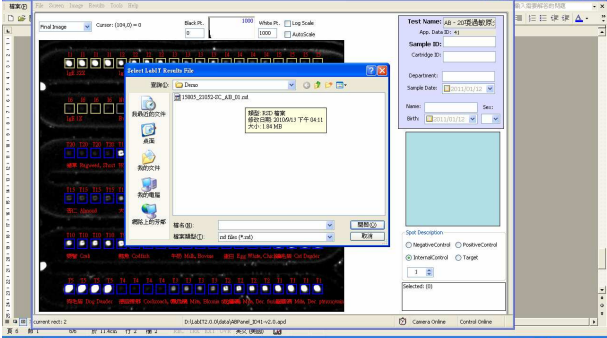
4.1.3 Leak Test (dark frame renew)

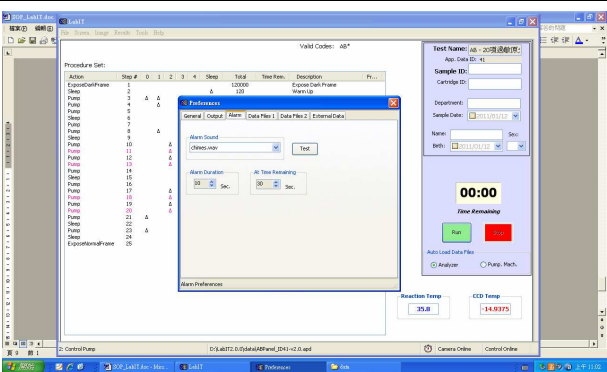
Items	Illustration	Notes
1		- Tools / System Test / Leak - Push the Test button to test the light leakage of the analyzer
2		- After 4 minutes, the results window will pop up. - The result passed, the test can be preceded. If results failed, then check the front door and retest. - Recommend to do the test before running experiment everyday

4.1.4 Data Files Saving

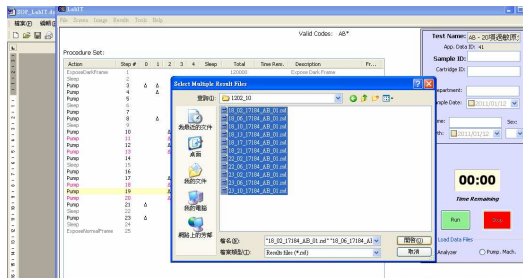
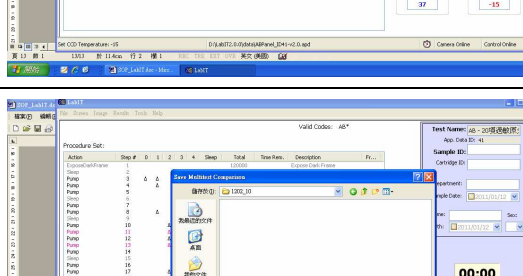
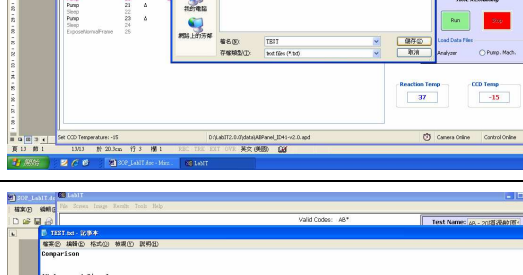
Items	Illustration	Notes
1		- Tools / Preference / Output - Select or create a folder for data saving in Auto Analysis Result Directory - All the results saved as a file called .rsd
2		- Tools / Preference / Output - Select a style sheet for the report format in Style sheet from a folder called Style sheet

4.1.5 Data Files Extracting & Alarm settings

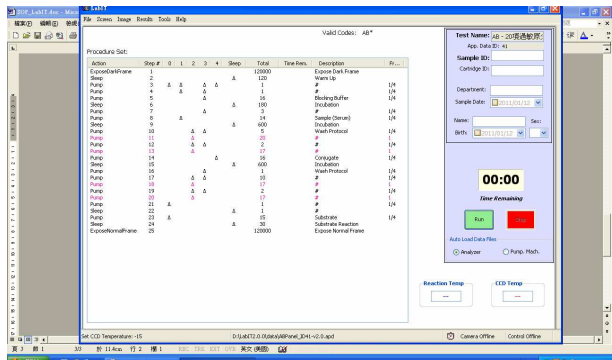
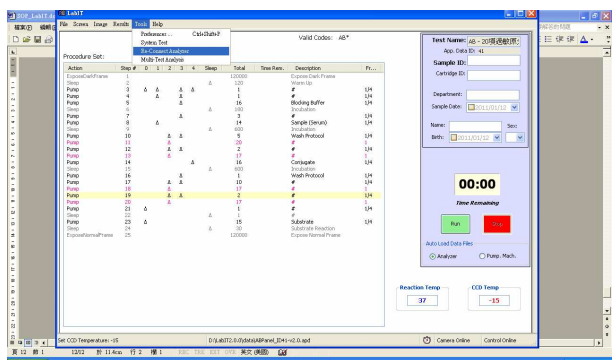
Items	Illustration	Notes
1		➤ Results / Extract Images - Extract the existed results
2		➤ Results / Extract Images ➤ Select a result (.rsd) that you want to extract ➤ The raw image can be showed by this function

Items	Illustration	Notes
1		➤ Tools / Preference / Alarm - Select the Alarm Sound, set the Alarm Duration, and Time Remaining for user own favor

4.1.6 Multi-Test Analysis

Items	Illustration	Notes
1		➤ Tools / Multi-Test Analysis Do the simple statistic math, and gather all the raw data together (formed as txt file)
2		➤ Tools / Multi-Test Analysis Select all the data (.rsd) which you want to analyze
3		➤ Tools / Multi-Test Analysis Save the result as txt file
4		➤ Tools / Multi-Test Analysis Open the file, and all the raw data will be showed up, including Mean, SD, CV

4.1.7 Re-Connect Analyzer

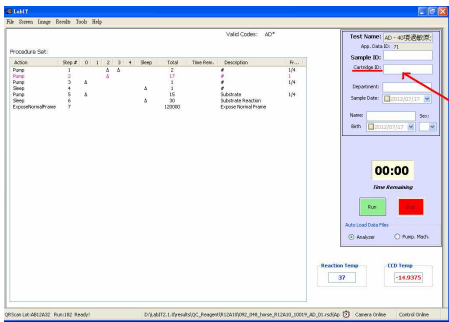
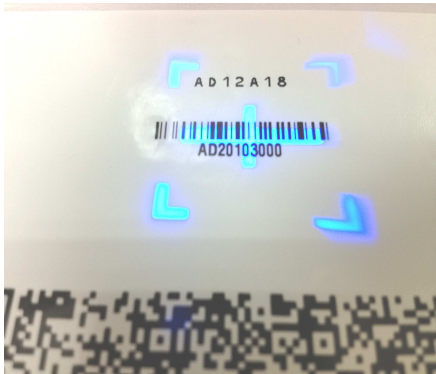
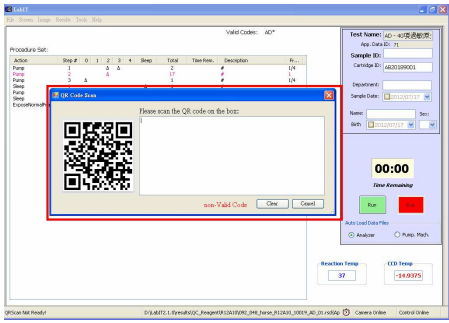
Items	Illustration	Notes
1		- Tools / Re-Connect Analyzer - If the Analyzer lost the link from RS232 or USB, the Reaction Temp or CCD Temp will not be showed up
2		- Tools / Re-Connect Analyzer - Reconnect the link to solve the problem - If the link still lost, then need to check if all the connectors connect properly

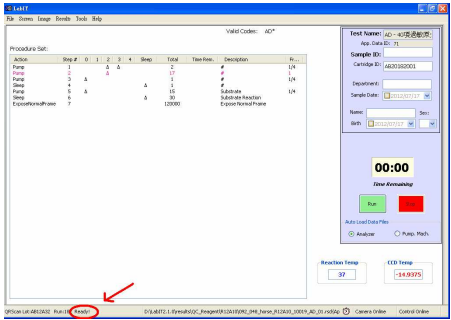
4.1.8 Terminate the Program and Analyzer

Note: CCD Camera needs to be warm up before shutting down. Unexpected shut down might damage the CCD Camera

Steps	Action
1	Turn off LabIT™
2	 The window of Warm Up process will pop up after turn off LabIT™, please wait for the Temp at least warm up upper 5°C
3	After the warm up completed, the window will be disappeared automatically
4	Turn off the Analyzer
5	Turn off the Computer

4.1.9 2D Barcode instruction procedures:

Steps	illustration	Description
1		➤ Drag mouse and point to the Cartridge ID column at LabIT Program patient information page.
2		➤ Open BioIC kit ➤ Use 2d barcode scanner to scan the barcode that shows inside the cover page of BioIC kit.
3		➤ The LabIT window will pop up automatically if the barcode batch information was not given to the LabIT software..
4		➤ Use 2D barcode scanner to scan 2D barcode ➤ Hold the scanner and toward to the middle of blue cross from the distance 10-20 cm. Please make sure the scanner cover the whole barcode area.

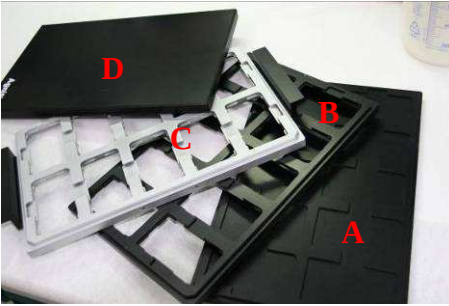
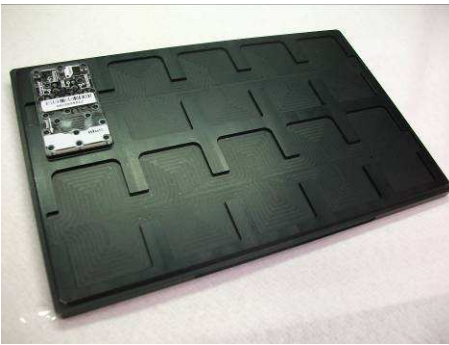
5		➤ The LabIT program will show “Ready” once the batch scanning has been completed.
6		➤ One barcode means one batch, ➤ Please repeat the scanning process as instructions if there are multiple sets of the barcodes.

4.2: Assay Procedures of BioIC Specific-IgE Allergen Detection Kit

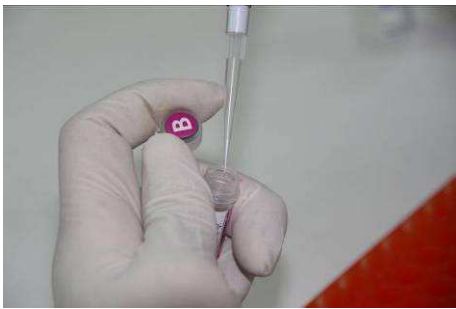
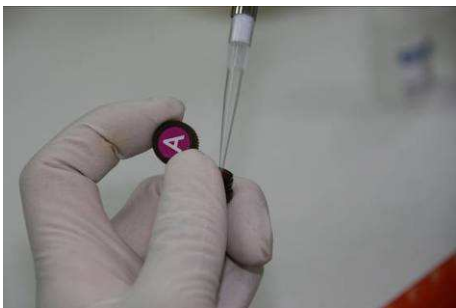
4.2.1 BioIC assay procedures

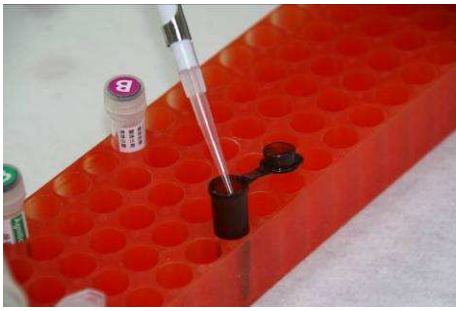
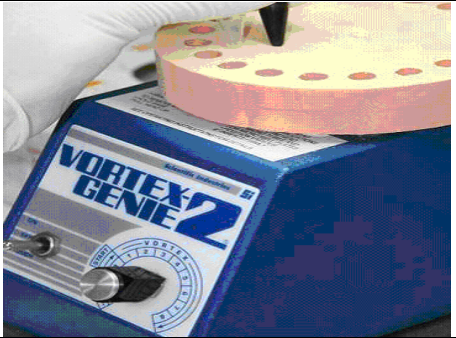
Note: Each assay procedure including clear photo and description, please make sure you have well understanding all the procedures before preparing the testing BioIC cartridges.

Steps	illustration	Description
1		➤ BioIC Allergen Specific-IgE Detection Kit ➤ The information of Manufacture Lot, Date, Expired Date and Storage Temperature are well indicated on the front label. ➤ Please making sure the kit is well storage at the right place as well as making sure the kit is not expired before testing
2		➤ Each reagent kit includes 20 cartridges, one package insert, and a set of reagent. ➤ Please read the package insert before start perform the testing.
3		➤ Reagents: one wash buffer, one blocking buffer, one set of stocking conjugate A, B, and one set of stocking substrate A, B

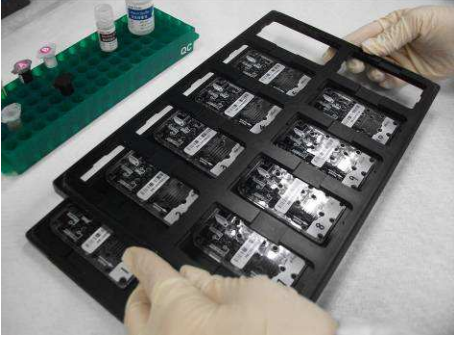
4		➤ Cartridge Loading Holder: This cartridge holder is designed to ease the serum sample and reagents loading into 10 cartridges at same time. ➤ Cartridge Loading Holder including 4 pieces: A = Tray: Place cartridges on the tray. B =Holder: Then place holder on top of tray. C = Fixer: Follow by fixer. This is special designed to fix cartridges and ease the reagents loading. D= Cover: Place the cover to avoid the exposure
5		➤ Open the aluminum bag and take out the new cartridge.
6		➤ Each aluminum bag contains one cartridge and one desiccant.
7		➤ Put the cartridge on the tray.

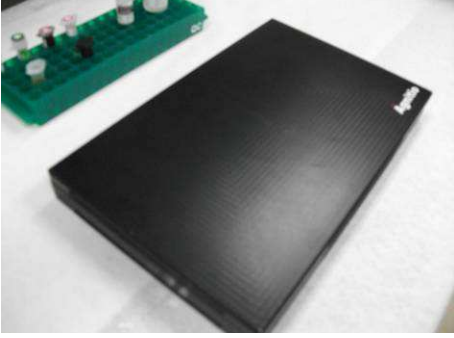
8		➤ Put the fixer on the top of tray.
9		➤ Mark the number on the cartridge if required
10		➤ Start to prepare the reagents ➤ Please read the package insert inside the kit first. ➤ Recommend to start from conjugate working solution preparation (1:1 mixing) ➤ Should concern about the dead volume. For Example, if you are preparing one test, 65 ul of conjugate stocking reagent A plus 65 ul of conjugate stocking reagent B will be recommended
11		➤ Add Conjugate stocking solution B

12		➤ Add Conjugate stocking solution A
13		➤ Well Mixing these two stocking solutions in eppendorf (or proper container)
14		➤ Preparing Substrate Working Solution (1:1 mixing)
15		➤ Add Substrate Stocking Solution B
16		➤ Add Substrate Stocking Solution A

17		➤ Well Mixed these two stocking reagents in another eppendorf (or proper container) ➤ Prepared Substrate Working Solution should be avoided the exposure
18		➤ Mixing thoroughly by vortex ➤ If there is no vortex, mixing by pipette
19		➤ In order to avoid the residual reagent in the eppendorf, centrifuge by micro-centrifuge again.
20		➤ Start to loading reagent into cartridge ➤ Loading wash buffer (620 ul)
21		➤ Make sure loading the reagents into the right positions

22		➤ Loading testing serum (100 ul)
23		➤ Loading blocking buffer (120 ul)
24		➤ Loading conjugate working solution (120 ul)
25		➤ Loading substrate working solution (120 ul)

26		➤ 10 cartridges can be prepared at one time
27		➤ Remove the fixer from the holder
28		➤ Another layer of holder ➤ There are two holders for 20 cartridges, however, only 10 cartridges prepared at a time will be suggested
29		

30		➤ Put the cover on the top of holder in order to avoid the light exposure
31		➤ All done ➤ Store these prepared cartridges covered with cartridge loading holder into refrigerator (2 ~ 8 °C) ➤ The stability of prepared cartridges are 8 hours
32		➤ Open the Analyzer and follow the arrow direction to insert the prepared cartridge into the Agnitio BioIC Analyzer.
33		➤ Make sure the cartridge is pushed to the end of the wall
34		➤ Close the front door and ready to test

4.2.2 Checking List before start using Agnitio BioIC Analyzer

Steps	Actions	Check
1	Turn on the computer	☐
2	Turn on the Analyzer	☐
3	Execute LabIT software	☐
4	Do the Leak Test	☐
5	Select or create a directory for data saving	☐
6	Check all the function are working properly including Reaction Temp and CCD Temp	☐
7	Scan the Cartridge ID	☐
8	Insert the Cartridge	☐
9	Input the Sample ID	☐
10	Input all the sample information	☐
11	Push the Run button to start the program	☐

5

5. Maintenance

5.1 Daily Maintenance

5.2 Weekly Maintenance

5.3 Annually Maintenance

	When to do	Who Should Do	Analyzer	Pumping Machine
5.1	Daily	User	✓	✓
5.2	Weekly	User	✓	✓
5.3	Annually	Distributor	✓	✓

5.1 Daily Maintenance

5.1.1 Analyzer & Pumping Machine

- Open Analyzer/Pumping Machine front door and push the pumping module switch manually.
- Clean the solenoids carefully with 75% alcohol
- Clean the Analyzer/Pumping Machine case with 75% alcohol
- Do not leave the cartridge in the cartridge slot after BioIC assay.



5.2 Weekly Maintenance

5.2.1 Analyzer & Pumping Machine

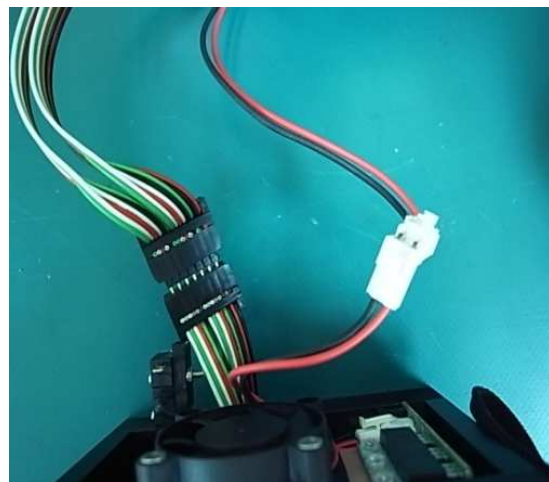
- Turn on analyzer power switch
- Check if all the fans function normally
- Start LabIT[™] program
- Check if analyzer default reaction temperature reach $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ in 30 minutes and CCD default temperature at $-15^{\circ}\text{C} \pm 1^{\circ}\text{C}$ (see below photos)
- Turn off the analyzer according to the turn off SOP (see section: 4.1.8 Terminate the Program and Analyzer).



- Wipe the cartridge slot with 75% alcohol with the gloves on.

5.3 Annually Maintenance

- Wipe the exterior and interior (including the insert slot) of Analyzer/Pumping Machine with 75% alcohol with the gloves on.
- Check the heat up temperature and the time consumed.
- Check all the fans' function are in well condition.
- Check with the Force Meter for the module.
 1. Get the module out of the Analyzer/Pumping Machine.
 2. Start LabIT.
 3. Connect the power extension from Analyzer and the signal cable as shown in the figure below

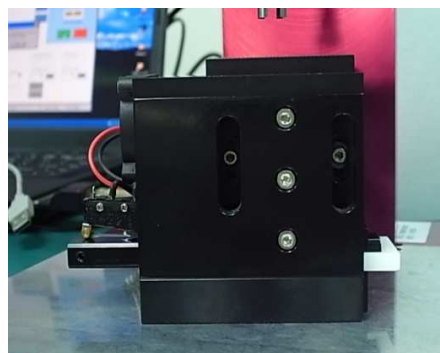


4. Turn on the Analyzer and Force Meter

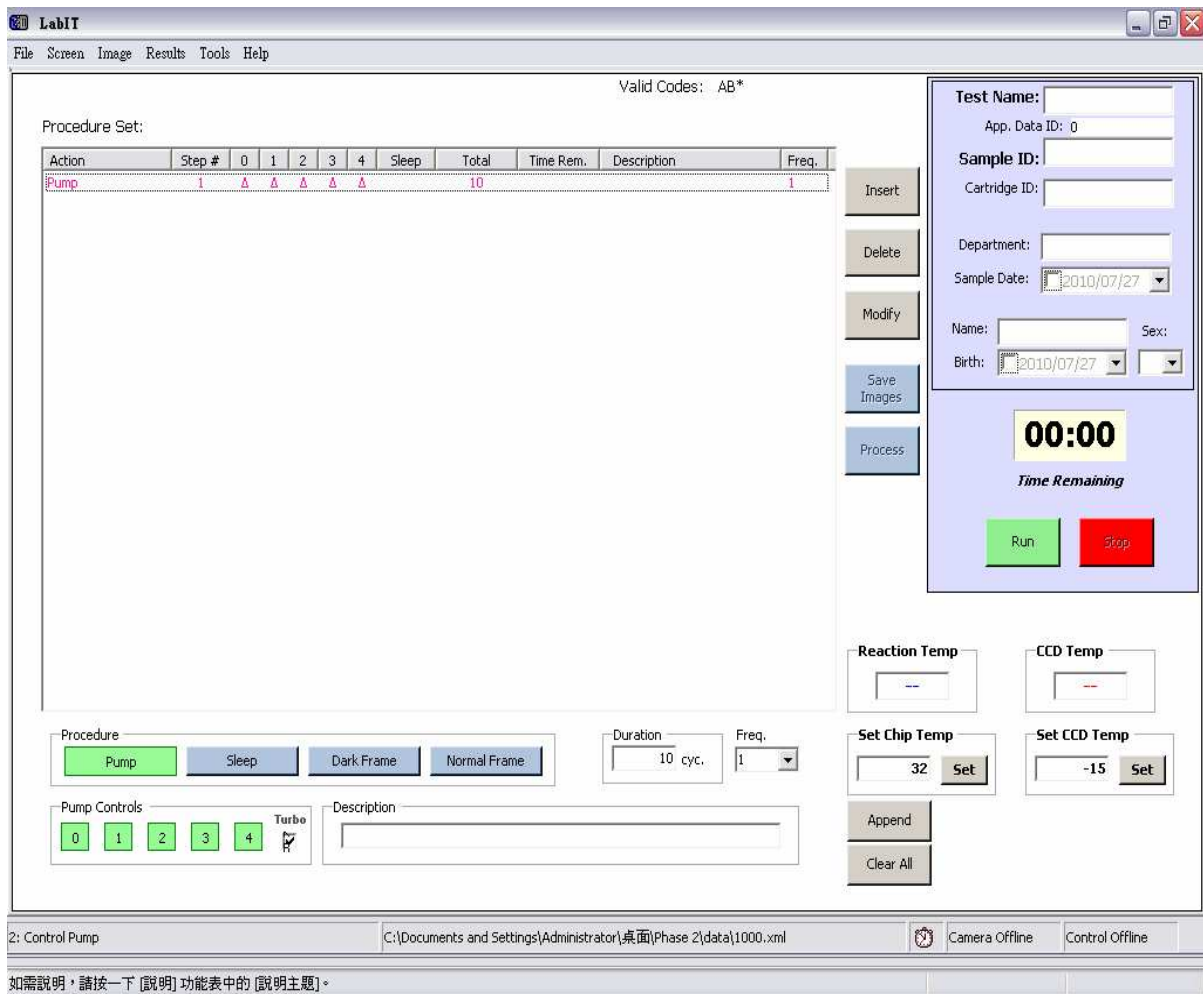


5. Check whether the module is operating normally, if not, please check all the connectors.

6. Push the switch in and lock it.



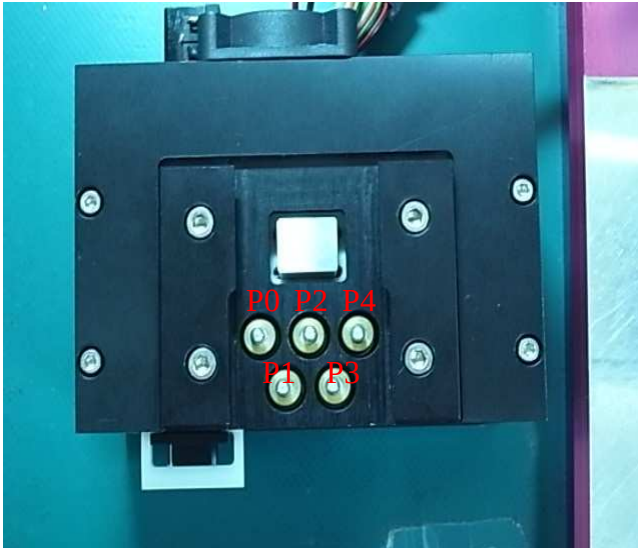
7. Push the bottom “ **PUMP**” in the procedure column, click all the bottoms under the Pump controls column (**0~4** & tick **Turbo**), adjust Duration to **10**, Frequency to **1** and push the bottom **Append** and **Run** it. (Refers to the figure next page)



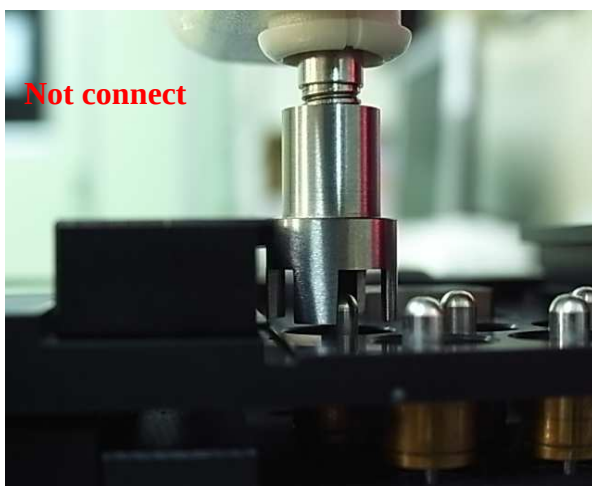
8. Set the Force Meter to zero, check the tightness of the connector and whether the platform is flat.

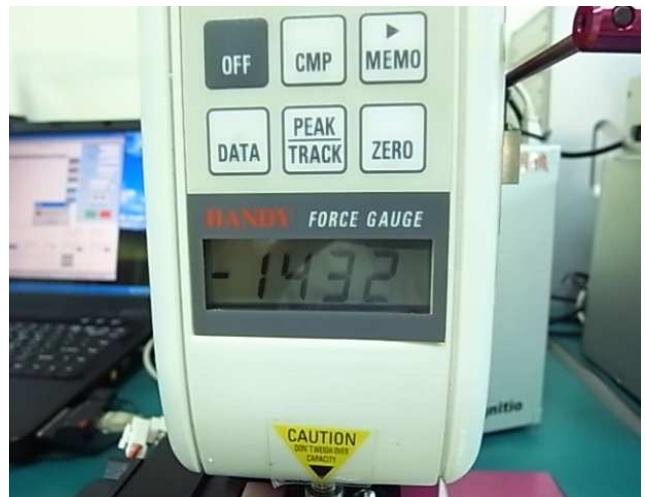


9. Pull down the switch, aim the connector to P0. (The scroll at the rear side can adjust the height of the connector)



※When adjusting the connector, if the connector touched the module, the screen of Force Meter will show negative number, if it's 0, shows that it's not reach the module yet.





10. Keep close for the connector and the module that the number remains 0 but it almost touch the surface of the module.

11. Check the number of the scroll and spin it anticlockwise to the same number.



12. Set the Force Meter to 0 again, and push **Peak track**.

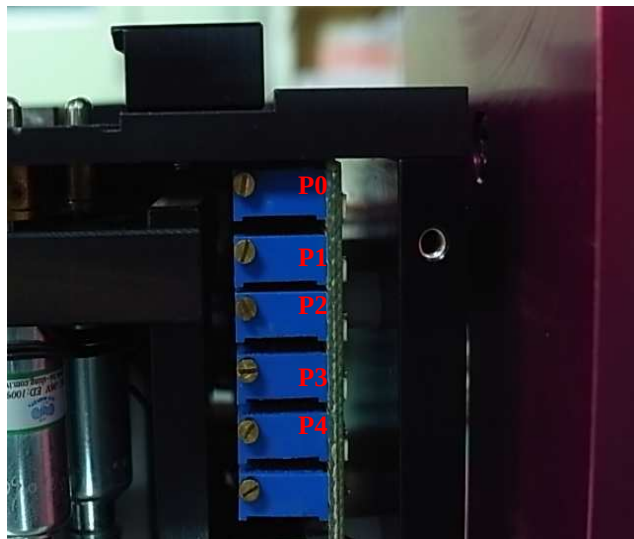


13. Use LabIT to check the force for each solenoid. (Push the bottom “**Clear ALL**” & “**PUMP**” in the procedure column, click P0 under Pump controls column & tick **Turbo**, adjust Duration to **1**, Frequency to **1** and push the bottom **Append** (step1) and push **Sleep** and push **Append** (step 2), keep repeat step 1 & 2 and **Run** it .

※ The range for the solenoids are followed:

Solenoid	P0	P1	P2	P3	P4
Force range(g)	120~125	120~125	130~135	120~125	120~125

14. If the solenoid is out of range, use the flathead screwdriver to adjust the resistance (spin clockwise to decrease, anticlockwise to increase).



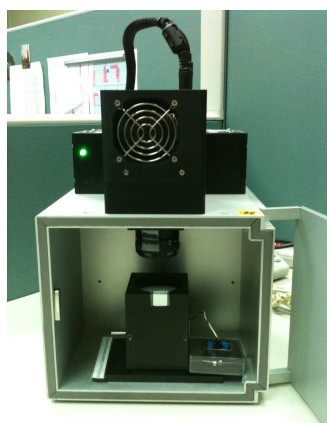
15. After adjust to the certain range, repeat the step 13 several times till it 's stable.

16. Finishing adjusting P0, repeat step 8 to 15 for other solenoids.

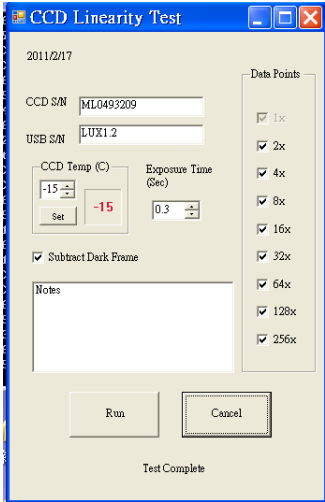
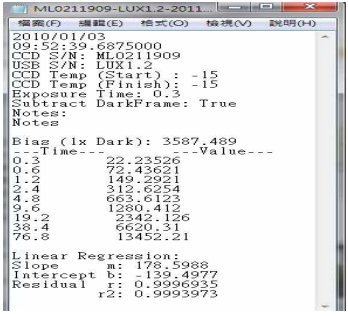
17. Turn off the Analyzer and Force Meter when finish and unbind the the power extension and the signal cable.

➤ CCD camera calibration platform examination

1. Take out the module from the Analyzer
2. Put the CCD camera calibration platform instead.



Turn on analyzer and the CCDtest program

		Put the photometer on the platform, push the switch on the left, adjust the value to 1.2, pull out switch and close the door.
		Set program: CCD S/N= CCD series number (shown on the CCD), USB S/N=1.2 , CCD Temp to -15° C, Exposure Time=0.3 , tick all boxes in the Data Points column (1x~256x), tick Subtract Dark Frame and run .
		The regular value range is: $R^2 > 0.997$, the value at 0.3 second > 20, the value at 19.2 second is between 1500 to 2400, recording the testing result.

➤ **BioIC Analyzer CCD leak test, position alignment & focus test**

Please refers to the page 25.

6

6. Trouble Shooting

6.1 BioIC Assay Report Fail Examples

6.2 BioIC System Error Messages & Troubleshooting

6.3 Error Messages During Running LabIT™ Program

6.4 Possible Error Messages During CCD Image Capturing

6.5 Possible Error Messages During Leak Test & Focus Test

6.1 BioIC Assay Report Fail Examples

Report Fail Example 1

Name: Aginto. Sex: Birth: Test Panel: AD - 40 ID: 1
 Dept.: Aginto. Cart. ID: AD20190056
 ID No.: Aginto Sample Date: 2012/10/16 12:04

Validation: Test Criteria Result
 Negative: NC0 < 0.5 AU Pass
 NC1 < 0.5 AU Fail
 NC2 < 0.5 AU Pass
 NC3 < 0.5 AU Pass
 Internal: IC6 > NC0 Pass
 Linearity: r^2 > 0.950 Pass

Internal Curve: 32 AU
 16 AU
 8 AU
 4 AU
 2 AU
 1 AU

Analysis Item	Result	Analysis Item	Result
AU	Class	AU	Class
Mold		Food and Others	
M1 Penicillium notatum	-	F25 Tomato	-
M2 Cladosporium herbarum	-	F31 Carrot	-
M3 Aspergillus fumigatus	-	F35 Potato, White	-
M5 Candida albicans	-	F84 Kiwi	-
M6 Alternaria alternata	-	F47 Garlic	-
Pollens		F13 Peanut	-
G2 Bermuda Grass	-	F14 Soybean	-
G6 Timothy Grass	-	F4 Wheat	-
W1 Ragweed, Short	-	F20 Almond	-
W6 Mugwort, Common	-	F41 Salmon	-
W12 Goldenrod	-	F3 Codfish	-
Mites		F23 Crab	-
D1 Mite, Der. pteronyssinus	-	F24 Shrimp	-
D2 Mite, Der. farinae	-	F37 Blue Mussel	-
D201 Mite, Biomia tropicalis	-	F2 Milk, Bovine	-
Epidermals		F300 Milk, Goat	-
E1 Cat Dander	-	F81 Cheddar Cheese	-
E5 Dog Dander	-	F1 Egg White, Chicken	-
E85 Chicken Feathers & Skin	-	F75 Egg Yolk, Chicken	-
E86 Duck Feathers & Skin	-	F45 Yeast, Bakers	-
I6 Cockroach, German	-	Reference Values:	
I207 Cockroach, Oriental	-	< 1 AU, (Not detected)	
Other		1-2 AU, Class 1 (Minimum)	
K82 Latex	-	2-4 AU, Class 2 (Low)	
		4-8 AU, Class 3 (Medium)	
		8-16 AU, Class 4 (High)	
		16-32 AU, Class 5 (Highest)	
		32+ AU, Class 6 (Highest)	

Summary:
 Class 6 Class 5 Class 4 Class 3 Class 2 Class 1

Report Fail Example 2

Name: Aginto. Sex: Birth: Test Panel: AD - 40 ID: 2
 Dept.: Aginto. Cart. ID: AD20190056
 ID No.: Aginto Sample Date: 2012/10/16 12:05

Validation: Test Criteria Result
 Negative: NC0 < 0.5 AU Pass
 NC1 < 0.5 AU Pass
 NC2 < 0.5 AU Pass
 NC3 < 0.5 AU Pass
 Internal: IC6 > NC0 Pass
 Linearity: r^2 > 0.950 Fail

Internal Curve: 32 AU
 16 AU
 8 AU
 4 AU
 2 AU
 1 AU

Analysis Item	Result	Analysis Item	Result
AU	Class	AU	Class
Mold		Food and Others	
M1 Penicillium notatum	-	F25 Tomato	-
M2 Cladosporium herbarum	-	F31 Carrot	-
M3 Aspergillus fumigatus	-	F35 Potato, White	-
M5 Candida albicans	-	F84 Kiwi	-
M6 Alternaria alternata	-	F47 Garlic	-
Pollens		F13 Peanut	-
G2 Bermuda Grass	-	F14 Soybean	-
G6 Timothy Grass	-	F4 Wheat	-
W1 Ragweed, Short	-	F20 Almond	-
W6 Mugwort, Common	-	F41 Salmon	-
W12 Goldenrod	-	F3 Codfish	-
Mites		F23 Crab	-
D1 Mite, Der. pteronyssinus	-	F24 Shrimp	-
D2 Mite, Der. farinae	-	F37 Blue Mussel	-
D201 Mite, Biomia tropicalis	-	F2 Milk, Bovine	-
Epidermals		F300 Milk, Goat	-
E1 Cat Dander	-	F81 Cheddar Cheese	-
E5 Dog Dander	-	F1 Egg White, Chicken	-
E85 Chicken Feathers & Skin	-	F75 Egg Yolk, Chicken	-
E86 Duck Feathers & Skin	-	F45 Yeast, Bakers	-
I6 Cockroach, German	-	Reference Values:	
I207 Cockroach, Oriental	-	< 1 AU, (Not detected)	
Other		1-2 AU, Class 1 (Minimum)	
K82 Latex	-	2-4 AU, Class 2 (Low)	
		4-8 AU, Class 3 (Medium)	
		8-16 AU, Class 4 (High)	
		16-32 AU, Class 5 (Highest)	
		32+ AU, Class 6 (Highest)	

Summary:
 Class 6 Class 5 Class 4 Class 3 Class 2 Class 1

6.2 Error Messages regarding BioIC Analyzer

Error Message	Solutions
CCD Temperature : -- /--	Step1 Click LabIT tools > Re-connect analyzer
	Step2 Reconnect USB port
	Step3 Log out LabIT program > Re-enter LabIT program
CCD Temperature : □ 43.66	Step1 Check whether the power supply of Analyzer connection is well connect
	Step2 Check if Laboratory external electricity shut down
	Step3 If the situation stay the same after restart it, please contact the technician from the manufacturer.
Reaction Temperature : 51	Step1 Close LabIT™ program
	Step2 Restart analyzer
	Step3 Start LabIT™ program again
Reaction Temperature : --	Step1 Enter Tools > Re-connect analyzer
	Step2 Reconnect R232
	Step3 Confirm if RS232 is linked with PC COM1
	Step4 Close LabIT™ program and restart it
Leak Test Failed	Check if front door closed properly. Or contact distributor/ manufacturer
	Please proceed the leak test
The CCD focus is incorrect	Please contact with the technician, do not adjust the focus unauthorized.

6.3 Error Messages during running LabIT™ program

Error Message	Solutions
Temperature Out of Range - Cannot Process	Wait until the system reach default temperature and restart the LabIT program
Time out Error in Step X	Check all connection ports , restart the program and perform new BioIC assay
Error Exposing DarkFrame - Run Aborted	Check all connection ports , restart the program and perform new BioIC assay
Error Exposing Frame - Run Aborted	Check all connection ports , restart the program and perform new BioIC assay
Procedure Stopped Prematurely - Analysis Aborted, Discard Cartridge Before Proceeding	Perform new BioIC assay
Door Open - Procedure Aborted Discard Cartridge Before Proceeding	Perform new BioIC assay
No Steps to run	Check LabIT™ program setting and restart the system
Door Open	Please close door prior to running

6.4 Possible Error Messages during CCD image capturing

Error Message	Solutions
Image Calibration Error (Continuing Without Calibration)	Please contact with the technician
Error Loading Calibration Image (Continuing Without Calibration)	Please contact with the technician
Missing Calibration Image (Continuing Without Calibration)	Please contact with the technician
Auto Alignment Failed Discard Cartridge Before Proceeding	Check if all the reagents loaded are correct and proceed the assay again
No Camera Images to Process	Check all the cable connection and the focus of CCD
Unable to Process Images	Check all the cable connection and the focus of CCD
No Application Data to run tests with	Loading the correct progeam and run it again
No Spots Defined - Image Analysis Aborted	Change the calibration image according to the CCD that the analyzer equip

6.5 Possible Error Messages during Leak Test & Focus Test

Error Message	Solutions
Door Open Test Aborted	Close front door and restart the leak test
Temperature(s) Out of Range	Check default temperature and restart the leak test
Leak Test Failed	Close front door and restart the leak test Contact manufacturer if problem still exist
Error Exposing Image(s) Test Aborted	Check all the cable connection and the focus of CCD
Error Exposing Frame	Check all the cable connections and proceed again
Invalid Region	Change the default CCD image capture area and restart the focus test